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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/831,591	08/13/2001	Tomoyasu Sugiyama		7048

7590 11/04/2003

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EXAMINER	
SISSON, BRADLEY L	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 11/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/831,591	SUGIYAMA ET AL.	
	Examin r	Art Unit	
	Bradley L. Sisson	1634	

-- Th MAILING DATE of this communication appears on the cover she t with th correspond nc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 June 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,11,13 and 14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,11,13 and 14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-5 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Mills et al.

3. It is noted that the publication of Miller et al., is newly cited prior art. It is also noted that this newly cited prior art was known to applicant prior to filing (see page 3, lines 21-22, of the specification) yet not disclosed to the Office in an Information Disclosure Statement. Applicant is reminded of their "acknowledged duty..." as set forth in their signed "Combined Declaration and Power of Attorney."

> I acknowledge the duty to disclose all information I know to be material to patentability in accordance with Title 37, Code of Federal Regulations, §1.56

4. Claims 1-5 and 13 are al drawn to "a hybridization probe." For convenience, a claim 1 (amended) is reproduced below.

1. (Amended) A hybridization probe that comprises a DNA capable of specifically hybridizing to a target nucleotide sequence, and an additional nucleotide sequence comprising one or more nucleotides selected from the group consisting of labeled nucleotides, labeled nucleotide derivatives, unlabeled nucleotides, and unlabeled nucleotide derivatives, wherein the additional ~~in which a nucleotide sequence comprising labeled nucleotides or nucleotide derivatives is added to a DNA to be labeled, the added~~ nucleotide sequence

a) comprises at least one nucleotide or nucleotide derivative ~~comprising nucleotides and/or nucleotide derivatives~~ having weaker affinity of hydrogen bonding in base pairing with bases of the target nucleotide sequence when compared with that ~~these~~ of hydrogen bonding in an a/t pair, in an a/u pair, and in a g/c pair;

b) comprises either or both of at least one labeled nucleotide and labeled nucleotide derivative; and

c) is ~~b) being~~ introduced into the DNA to be labeled through nucleotide-adding reaction with terminal transferase.

5. As seen above, the claim recites the limitation that the "nucleotide derivatives" are added via the action of a "terminal transferase." Accordingly, the claim, for purposes of examination, has been interpreted as a product-by-process claim. Attention is directed to MPEP 2113 [R-1], reproduced below.

2113 [R-1] Product-by-Process Claims

PRODUCT-BY-PROCESS CLAIMS ARE NOT LIMITED TO THE MANIPULATIONS OF THE RECITED STEPS, ONLY THE STRUCTURE IMPLIED BY THE STEPS

"[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) (Claim was directed to a novolac color developer. The process of making the developer was allowed. The difference between the inventive process and the prior art was the addition of metal oxide and carboxylic acid as separate ingredients instead of adding the more expensive pre-reacted metal carboxylate. The product-by-process claim was rejected because the end product, in both the prior art and the allowed process, ends up containing metal carboxylate. The fact that the metal carboxylate is not directly added,

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but is instead produced in-situ does not change the end product.).

6. Miller et al., page 22, left column, last two paragraphs, discloses production of PCR amplicons that comprise both normal dNTPs as well as derivatives thereof, wherein said nucleotide derivatives comprise inosinic acids as well as labeled nucleotides.

7. While applicant defies their product as a "hybridization probe," such speaks to intended use and does not speak to there being a material difference between the nucleic acid being claimed (a.k.a. a hybridization probe) and that disclosed in the prior art (an amplicon produced through polymerase chain reaction (PCR)). Accordingly, the amplicons produced by Miler et al., are considered to meet the structural requirements of the "hybridization probe" claimed instantly,

and as such, claims 1-5 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Mills et al.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 11 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chenchik et al. (US Patent 5,565,340) in view of Miller et al.

12. Chenchik et al., column 11, disclose kits that are to comprise reagents used in performing PCR, and that the kits may also comprise added reagents, including terminal transferase.

13. Chenchik et al., do not teach explicitly of including inosinic acids.

14. Miller et al. discloses performing PCR with inosinic acids.

15. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have included inosinic acids in the kit of Chenchik et al., as Miller et al., teaches explicitly of using inosinic acids in PCR, and the kit disclosed by Chenchik et al., is to comprise those very reagents that are used in performing PCR. In view of the detailed teachings, the ordinary artisan would have been both amply motivated and would have had a most reasonable expectation of success.

16. Accordingly, and in the absence of convincing evidence to the contrary, claims 11 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chenchik et al. (US Patent 5,565,340) in view of Miller et al.

Conclusion

17. Rejections that appeared in the prior Office action and that were not repeated hereinabove have been withdrawn.

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

19. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (703) 308-3978. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

21. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

22. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

B. L. Sisson

Bradley L. Sisson
Primary Examiner
Art Unit 1634

BLS
November 02, 2003